



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Elaine Merisko-Liversidge
Title: NOVEL NIFEDIPINE COMPOSITIONS
Appl. No.: 10/712,259
Filing Date: 11/14/2003
Examiner: Unassigned
Art Unit: 1615

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicant submits herewith on Form PTO/SB/08 a listing of documents known to Applicants in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56, except as noted below.

Documents A149 – A169 and A172 – A182 were cited by or submitted to the U.S. PTO in parent application Serial No. 09/337,675; filed 06/22/1999, Serial No. 10/276,400, filed 01/15/2003 and Serial No. 10/345,312, filed 01/16/2003. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection

with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003*.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Feb 20, 2004

By Michele M. Simkin

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: February 20, 2004

(use as many sheets as necessary)

Sheet 1 of 6

Complete if Known

Application Number	10/712,259
Filing Date	11/14/2003
First Named Inventor	Elaine Merisko-Liversidge
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	029318-0979

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	4,178,695		ERBEIA	12/18/1979	
	A2	4,540,602		MOTOYAMA ET AL.	09/10/1985	
	A3	4,616,047		LAFON	10/07/1986	
	A4	4,642,903		DAVIES	02/17/1987	
	A5	4,666,705		DECROSTA ET AL.	05/19/1987	
	A6	4,727,077		HAGA ET AL.	02/23/1988	
	A7	4,783,484		VIOLANTE ET AL.	11/08/1988	
	A8	4,814,175		TACK ET AL.	03/21/1989	
	A9	4,826,689		VIOLANTO ET AL.	05/02/1989	
	A10	4,851,421		IWASAKI ET AL.	07/25/1989	
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	A13	4,997,454		VIOLANTE ET AL.	03/05/1991	
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	A16	5,073,374		MCCARTY	12/17/1991	
	A17	5,098,907		KONDO ET AL.	03/24/1992	
	A18	5,110,605		ACHARYA	05/05/1992	
	A19	5,112,616		MCCARTY	05/12/1992	
	A20	5,118,528		FESSI ET AL.	06/02/1992	
	A21	5,145,683		RHODES	09/08/1992	
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	A23	5,178,878		WEHLING ET AL.	01/12/1993	
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	A26	5,200,192		WIMMER	04/06/1993	
	A27	5,215,758		KRISHNAMURTHY	06/01/1993	
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	A30	5,260,478		BACON ET AL.	11/09/1993	
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	A33	5,298,262		NA ET AL.	03/29/1994	
	A34	5,300,739		BITTAR	04/05/1994	
	A35	5,302,401		LIVERSIDGE ET AL.	04/12/1994	
	A36	5,318,767		LIVERSIDGE ET AL.	06/07/1994	
	A37	5,326,552		NA ET AL.	07/05/1994	
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	A39	5,336,507		NA ET AL.	08/09/1994	
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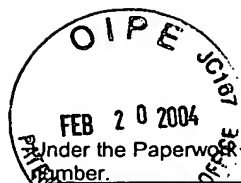
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: February 20, 2004 <i>(use as many sheets as necessary)</i>				Complete if Known													
Sheet 2 of 6				<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td>10/712,259</td> </tr> <tr> <td>Filing Date</td> <td>11/14/2003</td> </tr> <tr> <td>First Named Inventor</td> <td>Elaine Merisko-Liversidge</td> </tr> <tr> <td>Group Art Unit</td> <td>1615</td> </tr> <tr> <td>Examiner Name</td> <td>Unassigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>029318-0979</td> </tr> </table>		Application Number	10/712,259	Filing Date	11/14/2003	First Named Inventor	Elaine Merisko-Liversidge	Group Art Unit	1615	Examiner Name	Unassigned	Attorney Docket Number	029318-0979
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U.S. PATENT DOCUMENTS					
		U.S. Patent Document			
	A42	5,349,957		YUDELSON	09/27/1994
	A43	5,352,459		HOLLISTER ET AL.	10/04/1994
	A44	5,384,124		COURTEILLE ET AL.	01/24/1995
	A45	5,399,363		LIVERSIDGE ET AL.	03/21/1995
	A46	5,401,492		KELLAR ET AL.	03/28/1995
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	A48	5,429,824		JUNE	07/04/1995
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	A54	5,470,583		NA ET AL.	11/28/1995
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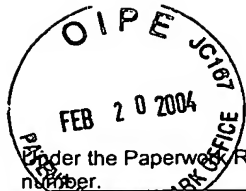
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Sheet 3 of 6

U.S. PATENT DOCUMENTS					
	U.S. Patent Document				
	A85	5,593,657	RUDDY ET AL.	01/14/1997	
	A86	5,595,761	ALLEN JR. ET AL.	01/21/1997	
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	A92	5,628,981	LIVERSIDGE ET AL.	05/13/1997	
	A93	5,631,023	KEARNEY ET AL.	05/20/1997	
	A94	5,635,210	ALLEN JR. ET AL.	06/03/1997	
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	A98	5,662,883	BAGCHI ET AL.	09/02/1997	
	A99	5,665,330	WONG	09/09/1997	
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	A103	5,709,886	BETTMAN ET AL.	01/20/1998	
	A104	5,716,642	BAGCHI ET AL.	02/10/1998	
	A105	5,718,388	CZEKAI ET AL.	02/17/1998	
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	A107	5,741,522	VIOLANTE ET AL.	04/21/1998	
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	A117	5,827,541	YARWOOD ET AL.	10/27/1998	
	A118	5,834,025	DE GARAVILLA ET AL.	11/10/1998	
	A119	5,851,553	MYERS ET AL.	12/22/1998	
	A120	5,862,999	CZEKAI ET AL.	01/26/1999	
	A121	5,866,163	MYERS ET AL.	02/02/1999	
	A122	5,869,098	MISRA ET AL.	02/09/1999	
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	A124	5,871,781	MYERS ET AL.	02/16/1999	
	A125	5,891,845	MYERS	04/06/1999	
	A126	5,972,389	SHELL ET AL.	10/26/1999	
	A127	6,045,829	LIVERSIDGE ET AL.	04/04/2000	

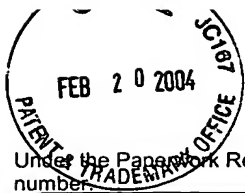
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Sheet	4	of	6		

U.S. PATENT DOCUMENTS						
	U.S. Patent Document					
	A128	6,068,858		LIVERSIDGE ET AL.	05/30/2000	
	A129	6,106,856		SQUILLANTE ET AL.	08/22/2000	
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	A134	6,264,922	B1	WOOD ET AL.	07/24/2001	
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	A136	6,270,806	B1	LIVERSIDGE ET AL.	08/07/2001	
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	A144	6,465,011	B2	LAW ET AL.	10/15/2002	
	A145	6,579,895	B2	KARIM ET AL.	06/17/2003	
	A146	6,592,903	B2	RYDE ET AL.	07/15/2003	
	A147	6,617,337	B1	WILCOX	09/09/2003	
	A148	2002/0012675	A1	JAIN ET AL.	01/31/2002	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office e ³	Number ⁴	Kind Code ⁵ (if known)				
	A149	WO	02/24193	A1	RTP PHARMA INC.	03/28/2002		
	A150	WO	02/098565		ELAN PHARMA INTERNATIONAL, LTD.	12/12/2002		
	A151	WO	98/46215	A1	CIMA LABS INC.	10/22/1998		
	A152	WO	96/24336	A1	NANOSYSTEMS L.L.C.	08/15/1996		
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	A155	EP	0 275 796	B2	CENTRE NAT RECH SCIENT (FR)	07/27/1988		ABS.
	A156	EP	0 636 365	A1	MCNEIL-PPC, INC.	02/01/1995		
	A157	WO	98/35666	A1	NANOSYSTEMS LLC	08/20/1998		
	A158	WO	98/07414	A1	RES. TRIANGLE PHARM. LTD.	02/26/1998		
	A159	WO	93/10760	A1	ALFATEC PHARMA GMBH ET AL.	06/10/1993		

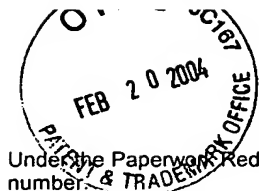
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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office e ³	Number ⁴	Kind Code ⁵ (if known)				
	A160	WO	93/10767	A1	ALFATEC PHARMA GMBH	06/10/1993		
	A161	WO	91/13612		BEECHAM GROUP PLC	09/1991		
	A162	WO	96/13251	A	SCHERER	05/09/1996		
	A163	WO	96/24339	A	NANOSYSTEMS	08/15/1996		
	A164	WO	01/45674	A	COCENSYS	06/28/2001		
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	A166	WO	00/27363		NANOSYSTEMS	05/18/2000		
	A167	WO	96/25918		NANOSYSTEMS LLC	08/29/1996		
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	A169	EP	0 262 560		ISHIHARA MINING & CHEMICAL CO. ET AL.	09/22/1987		

NON PATENT LITERATURE DOCUMENTS

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	A170	LINDAHL et al., "Characterization of Fluids from the Stomach and Proximal Jejunum in Men and Women," <i>Pharm. Res.</i> , 14(4): 497-502 (1997).	
	A171	<i>Physician's Desk Reference</i> , 57 th Edition, pp. 2622-2626 (2003).	
	A172	MATSUMOTO ET AL., "Physical Properties of Solid Molecular dispersions of Indomethacin with Poly(vinylpyrrolidone) and Poly(vinylpyrrolidone-co-vinyl-acetate) in Relation to Indomethacin Crystallization," <i>Pharmaceutical Research</i> (1999), Vol. 16, No. 11, pp. 1722-1728, XP000987250.	
	A173	HÜLSMANN ET AL., "Melt extrusion – an alternative method for enhancing the dissolution rate of 17β-estradiol hemihydrate," <i>European Journal of Pharmaceutics and Biopharmaceutics</i> (2000), Vol. 49, No. 3, pp. 237-242, XP004257163.	
	A174	VOJNOVIC ET AL., "Formulation and evaluation of vinylpyrrolidone/vinylacetate copolymer microspheres and griseofulvin," <i>J. Microencapsulation</i> (1993), Vol. 10, No. 1, pp. 89-99, XP000334996.	
	A175	BOGDANOVA ET AL., "Solid Dispersions of Isopropylantipyrin," <i>Labo-Pharma-Probl. Tech.</i> (1984), Vol. 32, No. 348, pp. 835-837, XP001097528.	
	A176	ZINGONE ET AL., "Characterization and dissolution study of solid dispersions of theophylline and indomethacin with PVP/VA copolymers," <i>STP Pharma Sciences</i> (1992), Vol. 2, No. 2, pp. 186-192, XP002111752.	
	A177	KONDO et al., "Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug," <i>Journal of Pharmaceutical Sciences</i> Vol. 83, No. 4, April 1994, pp. 566-70.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: February 20, 2004 (use as many sheets as necessary)		Application Number	10/712,259
		Filing Date	11/14/2003
		First Named Inventor	Elaine Merisko-Liversidge
		Group Art Unit	1615
		Examiner Name	Unassigned
Sheet	6	of	6
		Attorney Docket Number	029318-0979

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	A178	KONDO et al., "Improved Oral Absorption of a Poorly Water-Soluble Drug, HO-221, by Wet Bead Milling Producing Particles in Submicron Region," <i>Chemical & Pharmaceutical Bulletin</i> Vol. 41, No. 4, April 1993, pp. 737-40.	
	A179	KONDO et al., "Pharmacokinetics of a Micronized, Poorly Water-Soluble Drug, HO-221, in Experimental Animals," <i>Biological & Pharmaceutical Bulletin</i> Vol. 16, No. 8, August 1993, pp. 796-800.	
	A180	Plasdone® Povidone USP Technical Profile, International Specialty Products, 1999	
	A181	Plasdone® S-630 Technical Profile, International Specialty Products, 2000	
	A182	Kollidon® Grades Sheet, BASF	

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